Title 25. Health Services
Part I. Texas Department of Health
Chapter 97. Communicable Diseases
Repeal §§97.131- 97.134
Amendments §§97.1 - 97.4, 97.6, 97.139
New §§97.131 - 97.134, §§97.145 - 97.146

Adoption Preamble

The Texas Department of Health (department), adopts the repeal of existing §§97.131 - 97.134; amendment to §§97.1-97.4, 97.6, 97.139; and new §§97.131-97.134, and 97.145-97.146 concerning reporting requirements for sexually transmitted diseases (STD), which include Acquired Immune Deficiency Syndrome (AIDS), chancroid, *Chlamydia trachomatis* infection, gonorrhea, Human Immunodeficiency Virus (HIV) infection, and syphilis. Amended §§97.3 and 97.139; and new §§97.131 - 97.133 and 97.145 are adopted with changes to the proposed text as published in the July 31, 1998 issue of the Texas Register (23 Tex Reg 7692). Amended §§97.1 - 97.2, 97.4, and 97.6; new §§97.134 and 97.146; and repealed §§97.131-97.134 are adopted without change, and therefore the sections will not be republished.

Specifically, §§97.1 - 97.4 and 97.6 are amended to remove the definitions of HIV and AIDS from the general communicable disease definition section to eliminate redundancy, consistently define STD to include HIV and AIDS, and consistently list all the reportable STD together and alphabetically as AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, and syphilis. All definitions are numbered in new Texas Register format required to comply with Title 1, Administrative Code §91.1, effective February 17, 1998. Section §97.139 is amended to delete a reference to an obsolete phone number.

New §97.131 combines and modifies the definitions of HIV and AIDS, adds a definition of reportable STD which is consistent with the definition of these diseases by the Centers for Disease Control and Prevention, and allows for the definitions to reflect changes in testing technologies and disease knowledge when they occur in the future. In keeping with current definitions of AIDS, CD4+ lymphocyte cell counts of less than 200 cells/microliter or percentages less than 14% are reportable.

New §§97.132 - 97.134 combine all reportable STD, eliminating separate sections for HIV and AIDS. The sections allow for similar information to be reported on all STD, reducing the need for required reporters to submit different information for each STD. Specifically, all reportable STD, including HIV and AIDS, will be reported by name along with other minimally required information, regardless of the age of the patient. In keeping with current definitions of AIDS, CD4+ lymphocyte cell counts of less than 200 cells/microliter or percentages less than 14% are reportable by name. The adopted rules eliminate HIV infection reporting by a numerical code for persons aged 13 and older.

New sections §§97.134 and 97.146 add language on the confidentiality of all case reports and test results in addition to combining all reportable STD, eliminating separate sections for HIV and AIDS, and allowing for similar reporting of all STD. Section 97.146 adds references to the penalties for release or disclosure of a confidential test result.

New §97.145 provides for certain state-funded clinics to offer voluntary and affordable counseling and testing programs for HIV infection or refer clients to such programs, stipulating that all HIV testing sites funded by the department shall offer confidential and anonymous HIV testing on site.

The repeal, amendments, and new sections involve major revisions in the format and content of the sections. The amendments to existing sections and new sections will enable the reporting sources to more clearly identify the conditions and diseases which must be reported, define the minimal reportable information on these conditions and diseases, and describe the procedures for reporting to the local health authority or the department.

The department is making a minor change due to staff comment and to clarify a misprint in the Texas Register.

Change: Concerning §97.139 the words "(HIV)-Related Test Results to an Applicant for Insurance" should be part of the section title, not the section text as printed in the Texas Register.

The department received one hundred and eighty-five comments concerning the proposed sections. Seventy-nine of these communications supported the proposed changes, while one-hundred and six opposed the proposal. Following each comment is the department's response and any resulting change(s).

Comment: Concerning the definition of carrier in §97.1(2), three commenters recommended replacing the word "man" with either "mankind" or "human kind".

Response: The department disagrees with the commenters. As the proposed rule changes and preamble focused on reporting issues for STD, it would be inappropriate to make changes to §97.1(2), which is not directly related to STD, without further public comment. The comments have been forwarded to the appropriate program within the department. No change was made as a result of this comment.

Comment: Concerning §97.1, a commenter requested that the department include a definition for a tuberculosis suspect.

Response: The department declines to make any amendments to these sections. This comment was not relevant to the reporting of STD. No change was made as a result of this comment.

Comment: Concerning §97.3(c)(3), three commenters recommended that wording be revised to

clarify who is responsible for reporting changes in antibiotic therapy for tuberculosis patients.

Response: The department declines to make any amendments to these sections. These comments were not relevant to the reporting of STD. No change was made as a result of these comments.

Comment: Concerning §97.3(a)(2), three commenters recommended amending the phrase "repetitive test results" to read "repetitive diagnostic test results" in order to clarify that only diagnostic test results for STD should be reported multiple times for one patient. One commenter requested that the phrase "that relates to" be inserted to clarify that it is only repetitive diagnostic test results of infections that must be reported.

Response: The department agrees with the comments that the wording requires clarification: however, the department does not agree with the commenters' recommended language. Under the current rules, STD, including HIV and AIDS, are not listed as conditions for which repetitive test results should be reported. The department does not feel that reporting of STD will be compromised if the status quo continues. The department is deleting "... and sexually transmitted diseases, including AIDS and HIV infection." from the section.

Comment: Concerning §97.4(g), one commenter suggested including the phrase "using specimen submission form G-1 available from department."

Response: The department disagrees. The comment was not relevant to the reporting of STD.

Comment: Concerning §97.133, eight commenters expressed concern that reporting all CD4+ T lymphocyte cell counts constituted a burden on reporters and surveillance authorities. One commenter suggested a level of 400 cells/microliter and below, while two suggested a threshold of 200 cells/microliter or 14%. Two communications commented on the limited utility of CD4+ T lymphocyte cell counts as an HIV case finding device.

Response: The department agrees, and amended the proposed rules to return reporting thresholds for CD4+ T lymphocyte cell counts to the current level, making all CD4+ T lymphocyte cell counts which fall below 200 cells/microliter or 14% reportable by name. This amends the proposed rules to maintain laboratory-based AIDS reporting. Little information is available on the case finding efficiency of CD4+ T lymphocyte cell reporting.

Comment: Concerning §97.133, two commenters recommended making viral load measurements reportable instead of CD4+ T lymphocyte cell counts.

Response: The department disagrees with the recommendation. The definitions of AIDS and HIV infection are set by the Centers for Disease Control and Prevention (CDC), and change over time. In order to build flexibility into the reporting rules, the department declines to specifically reference viral load as reportable, for at this time, viral load is not part of the CDC HIV

definition. If the CDC amends the definition to include viral load measurements, those measurements would then be reportable. In order to accommodate reporting of AIDS, the department must maintain reporting by name of CD4+ $\,$ T lymphocyte cell counts which fall below 200 cells/microliter or 14%. The department has withdrawn the requirement that all CD4+ $\,$ T lymphocyte cell counts be reported, and has returned to the current requirements that only CD4+ $\,$ T lymphocyte cell counts which fall below 200 cells/microliter or 14% be reported.

Comment: Concerning §97.133, one commenter commented on the limited utility of CD4+ T lymphocyte cell counts as an HIV case finding device, noting that such tests are not indicative solely of AIDS/HIV infection, and commenting that reporting CD4+ T lymphocyte cell counts represents a breach of confidentiality for those patients who are not HIV infected.

Response: The department agrees in part. It is true that low CD4+ T lymphocyte cell counts may be found for reasons other than HIV infection/AIDS. However, reporting of counts which fall below 200 or 14% results in very few non-AIDS patients being reported through surveillance channels. Currently less than 10% of all CD4+ T lymphocyte cell counts reported to local surveillance authorities as suspect AIDS cases are for individuals who are not infected with HIV. Finally, as CD4+ T lymphocyte cell counts are handled with the same security measures and concern for confidentiality as other case reports within the surveillance system, there is no breach of the patient's confidentiality. No changes were made as a result of this comment.

Comment: Concerning §97.133, seventy-six commenters opposed named HIV infections because this may act to deter HIV testing among high-risk populations. Populations mentioned as especially vulnerable to testing deterrence effects were gay men (three commenters), African Americans (three commenters), Hispanics (three commenters), border populations (one commenter), substance users (one commenter), young people (two commenters), and women, especially women in abusive relationships (one commenter). Five commenters further expressed concern that any deterrence to testing would lead to more HIV infected individuals being unaware of their infections and unknowingly infecting others, thus increasing the number of infections.

Response: The department disagrees with the commenters. The department believes that the potential deterrent effect of named reporting of HIV infection may be blunted through active education of providers and the community about surveillance processes, data security measures, and the privileged nature of disease reporting information. The department will also continue to require state-wide access to anonymous testing for HIV, and has renewed its commitment to the availability of anonymous testing for HIV in §97.145(b). No change was made as a result of this comment.

Comment: Concerning §97.133, forty-one commenters recommended the proposal for named HIV reporting be withdrawn due to potential increases in discrimination in the professional and personal arenas against individuals living with HIV infection. These commenters described the devastating impact of discrimination, personal rejection, and the threat of being victimized by hate crimes on the health and well being of individuals with HIV.

Response: The department recognizes the current potential for discrimination, but disagrees that named reporting for HIV will increase discrimination. These commenters have incorrectly assumed that the information in the surveillance system is easily accessed by those outside the system. Surveillance data are not public information, they cannot be requested through open record requests, and they are not subject to reporting under the Freedom of Information Act or through subpoenas. Health and Safety Code §81.103 outlines the limited circumstances under which test results may be released and provides for criminal penalties for releases in violation of the law. Willful and inappropriate release of surveillance information is a Class A misdemeanor. The department acknowledges that individuals who are infected with HIV can face discrimination, but it is not the result of HIV surveillance case reporting, and cannot be remedied by continuing inadequate surveillance of HIV. No change was made as a result of this comment.

Comment: Concerning §97.133, twenty-seven commenters remarked that the current non-named HIV reporting system, in which HIV infections are reported by numeric code, was a desirable alternative to named reporting, and had not been given a sufficient test in Texas. These commenters urged the department to improve the non-named system (twenty-six commenters), with one commenter specifically urging the department to make efforts to make laboratories more compliant.

Response: The department disagrees with the commenters. The department initiated non-named reporting of HIV infection in April 1994. Evaluation of the system shows that reporting disease with out the name of the infected person fails to support the essential public health functions aimed at preventing the spread of disease. No change was made as a result of this comment.

Comment: Concerning §97.133, twenty-five commenters considered the reporting requirement for HIV to be an invasion of privacy.

Response: The department disagrees. Reporting of HIV and other sexually transmitted diseases by physicians and laboratories allows the department, and by extension, the community, to become aware of epidemics, to target resources, and to intervene in the spread of disease. Although these commenters may have philosophical objections to public health disease reporting databases and systems, the benefits to the public in terms of disease control and prevention are great. Since information on individuals with HIV infection is not available beyond the bounds of the surveillance system, the actual intrusion upon privacy is minimal. The great public good done with disease reporting information more than justifies this reporting requirement. No change was made as a result of this comment.

Comment: Concerning §97.133, eighteen commenters opposed named reporting of HIV infection based on possible breaches of confidentiality in the surveillance system. Four commenters remarked on the catastrophic effects of possible breaches on the health, safety, and well being of members of the affected communities. In addition, five commenters remarked that employees who handle surveillance data are not adequately trained or sufficiently sensitive to the importance of

the data to ensure that breaches would not occur.

Response: The department disagrees with the commenters. The named HIV data would be reported using the same protocols, practices, and data security systems that are used for other reportable sexually transmitted diseases, including AIDS. Although there have been more than 46,000 reported AIDS cases in Texas since 1983, the department is not aware of any breaches of confidentiality associated with the surveillance system. No change was made as a result of this comment.

Comment: Concerning §97.133, twenty-three commenters opposed named reporting of HIV infection due to the potential misuse of named HIV data by the following groups: the Texas Legislature (four commenters), the Immigration and Naturalization Service (one commenter), law enforcement personnel and agencies, including the Department of Public Safety (four commenters), hate groups (three commenters), insurance companies (two commenters), and employers (one commenter).

Response: The department disagrees with the commenters. Surveillance data are not public information. They cannot be requested by individuals or groups through open record requests, and they are not subject to reporting under the Freedom of Information Act or through subpoenas. The department does not allow access to named reporting databases by any state or federal agency for any reason, nor does it provide lists of infected individuals to any agencies. It is true that members of the Legislature could request confidential information for the purposes of developing legislation. However, any legislator requesting names of individuals reported with STD would have to justify why the names of infected individuals would be pertinent and why aggregate summary information about the cases reported in various geographical areas or demographic groups of interest would not suffice. Even then, the legislators using the data would be governed by the same confidentiality laws and standards as public health officials and health care providers and could not release the information requested. This restricted access means that the potential for misuse is minimal. No change was made as a result of this comment.

Comment: Concerning §97.133, eight commenters expressed the concern that HIV named reporting would cause a breakdown of hard-won trust between prevention outreach educators/counselors and their clients.

Response: The department is aware of this concern. The department is currently in consultation with the affected communities to minimize the negative impact of reporting changes on prevention and services efforts ongoing across the State. These concerns are a reason to strengthen education on the surveillance safeguards that protect the identity of infected individuals rather than to reject the named reporting of individuals with HIV infection. No change was made as a result of this comment.

Comment: Concerning §97.133, five commenters remarked that the proposal would increase the use of anonymous testing, thereby skewing HIV reporting data and raising questions of its

appropriateness for epidemiological purposes, and for purposes of allocation, advocacy, and planning.

Response: The department partially agrees. Based on the experiences of other states which have instituted named reporting of HIV infection, the department anticipates that the amount of anonymous testing will rise following the implementation of named reporting, but that it will return to the level characteristic of the state over time. The department further submits that named reporting will produce data that is more representative of the epidemic than the data currently being reported through the non-named system for HIV reporting. No change was made as a result of this comment.

Comment: Concerning §97.133, five commenters expressed concerns about HIV-infected individuals delaying access to medical treatment because of named reporting rules.

Response: The department disagrees. There is no evidence that named reporting delays access to treatment. These concerns are a reason to strengthen educational efforts aimed at HIV services providers and communities on the surveillance safeguards that protect the identity of infected individuals rather than to reject the named reporting of individuals with HIV infection. No change was made as a result of this comment.

Comment: Concerning §97.133, two commenters expressed doubts that local surveillance staffing levels were sufficient to handle the volume of HIV case work that named reporting would require, resulting in under reporting of cases.

Response: The department disagrees. Almost all local surveillance authorities have assured the department that with declining syphilis morbidity and the efficiency of adding new conditions to existing named reporting structures, the workload of HIV cases can be handled by existing staff through reprioritization of current caseloads. No change was made as a result of this comment.

Comment: Concerning §97.133, two commenters were concerned that named HIV reporting would make individuals testing less likely to disclose risky behaviors they practice for fear that those practices which are illegal in Texas will be reported to law enforcement, thus making reporting information on the mode of transmission less reliable.

Response: The department disagrees. Surveillance data are not available to law enforcement agencies, and cannot be used as evidence in legal proceedings. However, the perception that named reporting information could be used in this manner is a reason to strengthen educational efforts aimed at HIV services providers and communities on the surveillance safeguards that protect the identity of infected individuals rather than to reject the named reporting of individuals with HIV infection. No change was made as a result of this comment.

Comment: Concerning §97.133, two commenters urged caution in adopting named reporting of HIV due to potential harassment of HIV-positive individuals by counselors, disease intervention

specialists (DIS) and other providers attempting to link them into a care system. One commenter discussed such notifications in the context of triggering battering of women in abusive relationships.

Response: The department disagrees with the commenters. Partner elicitation/notification is an integral part of the process of informing someone of their HIV-positive status. The health department has a duty to discuss partners with infected clients and to warn partners of possible exposure to HIV, and the staff who carry out such notifications are highly trained specialists. This process is always voluntary. When health department staff conduct the notification, the process is strictly confidential. The original HIV-infected person's identity is never revealed to the partner. The potential for intimate violence exists during the partner notification process, but partner notification does not cause the violence. The potential for intimate violence already existed in the relationship prior to partner notification. Sometimes when a partner realizes they have been exposed to a deadly infection, they will choose to end a relationship that has involved infidelity, mistrust, or intimate violence. Counselors need to be aware of the potential for intimate violence and refer clients to appropriate sources of help when desired by the client. The department feels that the current guidelines for workers who contact HIV positive individuals are adequate, although the adoption of named reporting of HIV provides an opportunity for a recommitment to these guidelines and standards. No change was made as a result of this comment.

Comment: Concerning §97.133, one commenter urged the department to reject named reporting of HIV because the State bureaucracy was inherently insensitive to local community and program needs, and therefore this proposal is discordant with local concerns.

Response: The department disagrees. The need for reliable minimum estimates of HIV infection and epidemiologic profiles of HIV disease expressed by local communities and program administrators was one impetus for the proposed changes to the rules. No change was made as a result of this comment.

Comment: Concerning §97.133, one commenter objected to proposed changes due to the belief that HIV did not cause AIDS.

Response: The department disagrees. The weight of medical evidence argues against this comment. Furthermore, Texas law requires HIV infections to be reported to the department (Health and Safety Code §81.041). No change was made as a result of this comment.

Comment: Concerning §97.133, sixteen commenters indicated general opposition to named reporting of HIV infection.

Response: The department recognizes the general opposition, but disagrees that named reporting of HIV should not be implemented. Named reporting of HIV infection will allow information on HIV infection to be used to target resources, profile the epidemic, and prevent new infections without risk of disclosure of the identities of individuals who are reported through this system.

No change was made as a result of this comment.

Comment: Concerning §97.133, forty-six commenters suggested that named reporting of HIV will enhance access to care among infected individuals.

Response: The department agrees that HIV named reporting will enhance access to care by ensuring that services resources are appropriately distributed and by ensuring that public health resources are available to link infected individuals into care. Access to care is also enhanced by ensuring that voluntary confidential partner notification services are available to all individuals diagnosed with HIV disease, a practice which will place public health workers in contact with some infected individuals who are not yet aware of their status. No change was made as a result of this comment.

Comment: Concerning §97.133, forty commenters mentioned improved epidemiologic information as a benefit of named reporting of HIV infection.

Response: The department agrees. Improved HIV morbidity data will enable the department and the affected communities to use information on HIV infections in addition to information on AIDS cases to monitor changes in the HIV epidemic, allocate resources, and plan prevention and treatment programs. No change was made as a result of this comment.

Comment: Concerning §97.133, thirty-five commenters supported named reporting of HIV infection as in keeping with the department's public health duty. Twenty-six commenters wrote that the reporting change would allow the department to apply the same public health standards and approaches to HIV as are applied to other communicable diseases.

Response: The department agrees. The department agrees that HIV named reporting is in keeping with good public health practices and standards. No change was made as a result of this comment.

Comment: Concerning §97.133, seventeen commenters remarked that named reporting of HIV offered an opportunity to intervene in disease process and prevent infections, with four commenters including specific reference to arresting disease spread through more effective partner notification.

Response: The department agrees. HIV named reporting will enhance access to care by ensuring that service resources are appropriately distributed and by ensuring that public health resources are available to link infected individuals into care. Access to care is also enhanced by ensuring that voluntary confidential partner notification services are available to all individuals diagnosed with HIV disease, a practice which will place public health workers in contact with some infected individuals who are not yet aware of their status. No change was made as a result of this comment.

Comment: Concerning §97.133, four commenters made supportive remarks about the proposed

changes to the HIV surveillance system which mentioned the strong data security and confidentiality measures protecting HIV surveillance data.

Response: The department agrees. Named HIV surveillance information will flow through the same surveillance systems that have protected the names of more than 45,000 AIDS cases without a breach of confidentiality. Named reporting of AIDS cases has been in place since 1983. No change was made as a result of this comment.

Comment: Concerning §97.133, six commenters made supportive remarks about the proposed changes to the HIV surveillance system requiring the reporting of the names of individuals with confirmed HIV infections.

Response: The department agrees. The department agrees that HIV named reporting will enhance access to care by ensuring that service resources are appropriately distributed and by ensuring that public health resources are available to link infected individuals into care. Access to care is also enhanced by ensuring that voluntary confidential partner notification services are available to all individuals diagnosed with HIV disease, a practice which will place public health workers in contact with some infected individuals who are not yet aware of their status. No change was made as a result of this comment.

Comment: Concerning §97.145(b), one commenter suggested that the wording be modified to clarify that the choice of whether an anonymous or confidential HIV test will be performed is the sole province of the client, and that the procedures for each type of test will be fully reviewed with all persons seeking HIV testing at HIV testing sites funded by the department.

Response: The department agrees in part with the commenter. The department disagrees with the suggestion that language be added to reporting rules to require that these two types of tests be fully reviewed with clients of these providers. The department's "Counseling and Testing Guidelines" adequately address the idea of client-driven test decision making, and specifically guide counselors in the explanation to clients of the differences between confidential and anonymous HIV testing. The department feels that guidance of HIV test-decision counselors is best addressed outside reporting rules and is committed to providing this guidance. The department agrees that both confidential and anonymous testing should be available. The department has changed the language referencing the choice of test to read "All HIV testing sites funded by the Texas Department of Health shall offer confidential and anonymous HIV testing on site."

Comment: Concerning the proposal in general, twelve commenters expressed concern about the continued availability of anonymous testing for HIV.

Response: The department agrees with the commenters, and continues to support the widespread availability of anonymous testing. Department policy states that it must be made available at all HIV testing sites that contract with the department, and State law requires that all State-funded clinics must either provide anonymous testing on site, or provide referrals to sites which do. No

change was made as a result of this comment.

Comment: Concerning the proposal in general, one commenter urged the department to use a CDC "dual key" encryption technique which would prevent access to the names in surveillance databases without the cooperation of both the department and the CDC.

Response: The department disagrees with the commenter at this time. Although the CDC has discussed such encryption techniques at a number of public meetings, the technology does not currently exist. The department will examine use of such systems as they become available. No change was made as a result of this comment.

The following associations submitted comments in favor of the proposed rules: AIDS Outreach Center, RHD Memorial Medical Center, Trinity Medical Center, San Antonio Metropolitan Health District, United States Congressman Tom A. Coburn, St. Joseph Services Corporation, AIDS Foundation and Training Center for Texas and Oklahoma, California Department of Health, Texas Medical Association, Texas Society of Infectious Control Practitioners, Baylor College of Medicine, Houston Department of Health and Human Services, Triangle AIDS Network Inc., Dermatology Clinic of Paris, Amarillo Bi-City County Health District, Renaissance III Inc., Wichita Falls-Wichita County Public Health District, State Representative Peggy Hamric, and City of Lubbock Health Department. While the majority of these commenters supported the proposed rules in their entirety, some raised questions, offered comments for clarification purposes, and suggested clarifying language concerning specific provisions in the rules as discussed in the summary of comments. We also received communications from individuals generally supporting the proposed rules.

Comments received from associations which were generally not in favor of the proposed rules: American Civil Liberty Union of Texas, ACT Health Services, Advocacy Incorporated, AIDS Alliance of the Bay Area Inc., AIDS Housing Coalition Houston, AIDS Housing Houston Inc./Milam House, Amigos Volunteers in Education and Services Inc., The Assistance Fund, Bering Community Service Foundation, The BLOCK, Body Positive/Houston, Career and Recovery Resources, Center for AIDS, Thomas Street Health Center Council, Houston Buyer's Club, Houston Center for Independent Living, Jewish Family Service, Metropolitan Community Church of the Resurrection, Mother's Voices, National Association for the Advancement of Colored People, Over the Hill, Inc., People With AIDS Coalition, Program for Wellness Restoration, SEARCH Homeless Project, Steven's House, Vita-Living, Inc., WAM Foundation, The Parkland Health and Hospital System, Committee to Establish UI in HIV Testing and Reporting, State Representative Debra Danburg, AIDS Resources Center of Dallas, Foundation for Human Understanding, AIDS Services of Dallas, AIDS Foundation of Houston, Houston City Council Member Annise D. Parker, Valley AIDS Council, South Plains AIDS Resources Center, The Montrose Counseling Center, Montrose Clinic, City of Houston Council Member John Castillo, National Latino Lesbian and Gay Organization, and Southwest AIDS Committee Inc. of El Paso. All of these commenters were not against the rules in their entirety, with most expressing concern over named reporting of HIV infection. Some of them expressed concerns,

asked questions and suggested recommendations for change as discussed in the summary of comments. We also received communications from individuals generally opposing the portions of the proposed rules addressing HIV reporting.

Two associations commented on the proposed rules that were neither for nor against the rules in their entirety. However, they raised questions and offered comments for clarification purposes. The commenters were: Association of Texas Hospitals and Health Care Organizations and Bering Community Foundation. These comments are also discussed in the summary of comments.

The repeal, amendments, and new sections are adopted under the Communicable Disease Prevention and Control Act, Health and Safety Code, Chapter 81: §81.041 which requires the department to obtain reports of AIDS and HIV, and to identify other reportable diseases; §81.044, which requires the board to prescribe the form and method of reporting; and §81.004 which allows the Texas Board of Health (board) to adopt rules as necessary to administer the chapter. Amendments are also adopted under the Human Immunodeficiency Virus Services Act, Health and Safety Code Chapter 85, §85.032 which provides the board with the authority to adopt rules to administer a program of state grants to community organizations. The amendments, repeal and new sections are adopted under §12.001, which provides the board with the authority to adopt rules for the performance of every duty imposed by law on the Texas Board of Health, the Texas Department of Health, and the Commissioner of Health.

Sections adopted for repeal:

§97.131 Definitions.

§97.132 Who Shall Report Sexually Transmitted Diseases.

§97.133 Reporting Information for Sexually Transmitted Diseases.

§97.134 How to Report Sexually Transmitted Disease.

Legend:

<u>Double underline</u> = New language not proposed

[Bold, underline and brackets] = Proposed new language now being deleted

[Bold and brackets] = Final language now being deleted

Regular print = Current language incorporating all proposed changes for final adoption

§97.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

- (1) Act Communicable Disease Prevention and Control Act, Health and Safety Code, Chapter 81.
- (2) Carrier An infected person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source or reservoir for the infection of man.
- (3) Case As distinct from a carrier, the term "case" is used to mean a person in whose tissues the etiological agent of a communicable disease is lodged and which usually produces signs or symptoms of disease. Evidence of the presence of a communicable disease may also be revealed by laboratory findings.
 - (4) Commissioner Commissioner of Health.
- (5) Communicable disease An illness due to an infectious agent or its toxic products which is transmitted directly to a well person from an infected person or animal, or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.
- (6) Contact A person or animal that has been in such association with an infected person or a contaminated environment so as to have had opportunity to acquire the infection.
 - (7) Department Texas Department of Health.
- (8) Disinfection Destruction of infectious agents outside the body by chemical or physical means directly applied.
- (9) Epidemic or outbreak The occurrence in a community or region of a group of illnesses of similar nature, clearly in excess of normal expectancy, and derived from a common or a propagated source.
- (10) Exposure--A situation or circumstance in which there is significant risk of becoming infected with the etiologic agent for the disease involved.

(11) Health authority - A physician designated to administer state and local laws relating to public health under the Local Public Health Reorganization Act, Health and Safety Code, Chapter 121. The health authority, for purposes of these sections, may be:

(A) a local health authority:

- (i) director of a local health department; or
- (ii) physician as appointed by the Commissioner of Health if there is no director of a local health department.
- (B) a regional director of the Texas Department of Health if no physician has been appointed by the Commissioner of Health as a local health authority.
- (12) Hospital laboratory Any laboratory that performs laboratory test procedures for a patient of a hospital either as a part of the hospital or through contract with the hospital.
 - (13) Outbreak See definition of epidemic in this section.
- (14) Penicillin resistant *Streptococcus pneumoniae Streptococcus pneumoniae* with a penicillin minimum inhibitory concentration (MIC) of 2 μ g/mL or greater (high level), and an intermediate level resistance of 0.1- 1 μ g/mL.
- (15) Physician A person licensed by the Texas State Board of Medical Examiners to practice medicine in Texas.
- (16) Regional director The physician who is the chief administrative officer of a region as designated by the department under the Local Public Health Reorganization Act, Health and Safety Code, Chapter 121.
 - (17) Report Information that is required to be provided to the department.
- (18) Report of a disease The notification to the appropriate authority of the occurrence of a specific communicable disease in man or animals, including all information required by the procedures established by the department.
- (19) Reportable disease Any disease or condition that is required to be reported under the Act or by these sections. See §97.3 of this title (relating to What Condition To Report and What Isolates To Report or Submit). Any outbreak, exotic disease, or unusual group expression of illness which may be of public health concern, whether or not the disease involved is listed in §97.3 of this title, shall be considered a "reportable disease."
 - (20) Significant risk A determination relating to a human exposure to an etiologic agent

for a particular disease, based on reasonable medical judgements given the state of medical knowledge, relating to the following:

- (A) nature of the risk (how the disease is transmitted);
- (B) duration of the risk (how long an infected person may be infectious);
- (C) severity of the risk (what is the potential harm to others); and
- (D) probability the disease will be transmitted and will cause varying degrees of harm.
- (21) School administrator The city or county superintendent of schools, or the principal of any school not under the jurisdiction of a city or county board of education.
- (22) Specimen Submission Form G-1 A multipurpose specimen submission form available from the Texas Department of Health, Bureau of Laboratories, 1100 West 49th Street, Austin, Texas, 78756-3199.
- (23) Vancomycin resistant *Enterococcus* species *Enterococcus* species with a vancomycin MIC greater than 16 micrograms per milliliter (μ g/mL) or a disk diffusion zone of 14 millimeters or less. Vancomycin intermediate Enterococcus (e.g., *Enterococcus casseliflavis* and *Enterococcus gallinarum*) with a vancomycin MIC of 8μ g/mL 16μ g/mL do not need to be reported.
- (24) Vancomycin resistant *Staphylococcus aureus* and vancomycin resistant coagulase negative *Staphylococcus* species For the purposes of reporting, *Staphylococcus aureus* or a coagulase negative *Staphylococcus* species with a vancomycin MIC of $8\mu g/mL$ or greater.
- §97.2. Who Shall Report.
 - (a) -(c) (No Change.)
- (d) School authorities, including a superintendent, principal, teacher, school health official, or counselor of a public or private school and the administrator or health official of a public or private institution of higher learning should report as required by these sections those students attending school who are suspected of having a reportable disease. School authorities are exempt from reporting sexually transmitted diseases, including acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infection, in accordance with \$97.132(5) (relating to Who Shall Report Sexually Transmitted Diseases.)
 - (e) (g) (No Change.)
- §97.3. What Condition To Report and What Isolates To Report or Submit.

- (a) Identification of reportable conditions.
 - (1) (No Change.)
- (2) Repetitive test results from the same patient do not need to be reported except for mycobacterial infections [and sexually transmitted diseases, including AIDS and HIV infection].
 - (b) (No Change.)
- (c) Minimal reportable information requirements. The minimal information that shall be reported for each disease is as follows:
 - (1) (No Change.)
- (2) AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, and syphilis shall be reported in accordance with §§97.132 97.135 of this title (relating to Sexually Transmitted Diseases, including AIDS and HIV infection);
- (3) for tuberculosis name, present address, present telephone number, age, date of birth, sex, race and ethnicity, physician, disease, type of diagnosis, date of onset, antibiotic susceptibility results, initial antibiotic therapy, and any change in antibiotic therapy;
- (4) for all other reportable conditions listed in subsection (b)(1) of this section -name, present address, present telephone number, age, date of birth, sex, race and ethnicity, physician, disease, type of diagnosis, date of onset, address, and telephone number;
- (5) for all isolates of Enterococcus species and all isolates of Streptococcus pneumoniae regardless of resistance patterns numeric totals at least quarterly; and
- (6) for vancomycin resistant *Enterococcus* species; penicillin resistant *Streptococcus pneumoniae*; vancomycin resistant *Staphylococcus aureus*; vancomycin resistant coagulase negative *Staphylococcus* species, name, city of submitter, date of birth or age, sex, anatomic site of culture, and date of culture.
 - (d) (No Change.)
- §97.4. When to Report a Condition or Isolate; When to Submit an Isolate.
 - (a) (b) (No Change.)
- (c) AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, and syphilis shall be reported in accordance with §§97.132 97.135 of this title (relating to Sexually

Transmitted Diseases including AIDS and HIV infection);

- (d) Tuberculosis antibiotic susceptibility results should be reported by laboratories no later than one week after they first become available.
- (e) For all other reportable diseases not listed in subsections (a)-(c) of this section, reports of disease shall be made no later than one week after a case or suspected case is identified.
- (f) For *Enterococcus* species; vancomycin resistant *Enterococcus* species; *Streptococcus* pneumoniae; and penicillin resistant *Streptococcus* pneumoniae reports shall be made no later than the last working day of March, June, September, and December.
- (g) All Neisseria meningitidis from normally sterile sites, all vancomycin resistant *Staphylococcus aureus*, and all vancomycin resistant coagulase negative *Staphylococcus* species shall be submitted as pure cultures to the Texas Department of Health, Bureau of Laboratories, 1100 West 49th Street, Austin, Texas 78756-3199 as they become available.
- §97.6. Reporting and Other Duties of Local Health Authorities and Regional Directors.
 - (a) (No change.)
- (b) Those reportable conditions identified as public health emergencies in §97.4(a) of this title (relating to When to Report a Condition or Isolate; When to Submit an Isolate) shall be reported immediately to the department by telephone.
- (c) AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection and syphilis shall be reported in accordance with §§97.132 97.135 of this title (relating to Sexually Transmitted Diseases including AIDS and HIV infection).
- (d) The local health authority or the department's regional director shall collect reports of disease and transmit the following information at weekly intervals as directed by the department:
 - (1) for chickenpox numerical totals by age group; and
- (2) for reportable diseases not listed in subsection (c) or (d)(1) of this section by name, city, age, date of birth, sex, race and ethnicity, physician, disease, type of diagnosis, date of onset, address, and telephone number.
 - (e) Transmittal may be by telephone, mail, courier, or electronic transmission.
- (1) If by mail or courier, the reports shall be on a form provided by the department and placed in a sealed envelope addressed to the attention of the appropriate receiving source and

marked "Confidential."

- (2) If by electronic transmission, including facsimile transmission by telephone, the local health authority or the department's regional director must obtain prior approval of the manner and form of the transmission from the commissioner of health (commissioner) or his/her designee. Any electronic transmission of the reports must provide at least the same degree of protection against unauthorized disclosure as those of mail or courier transmittal.
- (f) The health authority shall notify health authorities in other jurisdictions of a case or outbreak of a communicable disease that has been reported if the case resides in another jurisdiction or there is cause to believe transmission of a disease may have occurred in another jurisdiction. The department shall assist the health authority in providing such notifications upon request. The health authority of the area where the case or outbreak is diagnosed shall report the case or outbreak to the department on the same basis as other reports.
- (g) The health authority upon identification of a case or upon receipt of notification or report of disease shall take such action and measures as may be necessary to conform with the appropriate control measure standards. The health authority may upon identification of a case or upon report of a communicable disease in a child attending a public or private child-care facility or a school notify the owner or operator of the child-care facility or the school administrator. The commissioner is authorized to amend, revise, or revoke any control measure or action taken by the health authority if necessary or desirable in the administration of a regional or statewide public health program or policy.
- (h) The health authority is empowered to close any public or private child-care facility, school or other place of public or private assembly when in his or her opinion such closing is necessary to protect the public health; and such school or other place of public or private assembly shall not reopen until permitted by the health authority who caused its closure.

Legend:

<u>Double underline</u> = New language not proposed

[Bold, underline, and brackets] = Proposed new language now being deleted Regular print = Current language incorporating proposed changes for final adoption

§97.131. Definitions.

The following words and terms when used in these sections shall have the following meanings unless the context clearly indicates otherwise.

- (1) AIDS and HIV Infection Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection are as defined by the Centers for Disease Control and Prevention of the United States Public Health Service and in accordance with the Health and Safety Code §81.101. The publication designating the most current definition may be requested from: Texas Department of Health, HIV/STD Epidemiology Division, 1100 West 49th Street, Austin, Texas 78756.
- (2) Chancroid, *Chlamydia trachomatis* infection, gonorrhea and syphilis These diseases are as defined by the Centers for Disease Control and Prevention of the United States Public Health Service. The publication designating the most current definition may be requested from: Texas Department of Health, HIV/STD Epidemiology Division, 1100 West 49th Street, Austin, Texas 78756.
- (3) Sexually transmitted disease An infection, with or without symptoms or clinical manifestations, that is or may be transmitted from one person to another during or as a result of sexual relations, and that produces or might produce a disease in, or otherwise impair, the health of either person, or might cause an infection or disease in a fetus in utero or a newborn. Acquired Immune Deficiency Syndrome (AIDS), chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, and syphilis are sexually transmitted diseases reportable under these rules.

§97.132. Who Shall Report Sexually Transmitted Diseases.

The following shall provide information on cases of AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, or syphilis:

- (1) A physician or dentist shall report each patient that is diagnosed or treated for AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, or syphilis. A physician or dentist may designate an employee of the clinic, including a school based clinic or physician's/dentist's office to serve as the reporting officer. A physician or dentist who can assure that a designated or appointed person in their clinic or office is regularly reporting every occurrence of these diseases does not have to submit a duplicate report.
 - (2) The chief administrative officer of a hospital, a medical facility or a penal institution

shall report each patient who is medically attended at the facility and is diagnosed with AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, or syphilis. The chief administrative officer may designate an employee of their institution to serve as the reporting officer. A chief administrative officer who can assure that a designated or appointed person in their institution is regularly reporting every occurrence of these diseases does not have to submit a duplicate report. Hospital laboratories may report through the reporting officer or independently in accordance with the hospital's policies and procedures.

- (3) Any person in charge of a clinical laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of a blood specimen or any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, or syphilis, including a CD4+ T lymphocyte cell count <u>below 200 cells/microliter or a CD4+ T lymphocyte percentage of less than 14%</u>, shall report according to §97.133 of this title (relating to Reporting Information for Sexually Transmitted Diseases).
- (4) The medical director or other physician responsible for the medical oversight of a counseling and testing site or a community-based organization shall report each patient that is diagnosed with AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection, or syphilis. The medical director or clinic physician may designate an employee of the counseling and testing site or community-based organization to serve as the reporting officer. A medical director or clinic physician who can assure that a designated or appointed person from their counseling and testing site or community-based organization is regularly reporting according to \$97.133 of this title every occurrence of these diseases does not have to submit a duplicate report.
- (5) School administrators, as defined in §97.1 of this title (relating to Definitions), who are not medical directors meeting the criteria described in this section, are exempt from reporting AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection or syphilis.
- (6) Failure to report a reportable disease is a Class B misdemeanor under the Texas Health and Safety Code, §81.049.
- §97.133. Reporting Information for Sexually Transmitted Diseases.

The following information, at a minimum, shall be reported for any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of AIDS, chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection or syphilis, including a CD4+ T <u>lymphocyte</u> cell count <u>below 200 cells/microliter or a CD4+ T lymphocyte percentage of less than 14%:</u>

(1) laboratories: name, address, city, county and zip code of residence, date of birth (month, day, year), sex, race/ethnicity, date test(s) performed, type(s) of test(s) performed, result of the test(s) or CD4+ T lymphocyte cell count, physician's name, physician's/clinic's address

and telephone number. Positive tests and [all] CD4+ T <u>lymphocyte</u> cell counts <u>below 200</u> cells/microliter or less than 14% shall be reported and;

- (2) others as described in §97.132 of this title (relating to Who Shall Report Sexually Transmitted Diseases): name, address, city, county and zip code of residence, date of birth (month, day, year), sex, race/ethnicity, diagnosis, stage of diagnosis for syphilis only, date test(s) performed, type(s) of test(s) performed, and result(s) of test(s) or CD4+ T <u>lymphocyte</u> cell count <u>below 200 cells/microliter or a CD4+ T lymphocyte percentage of less than 14%</u>, treatment provided, physician's name, physician's/clinic's address and telephone number.
- §97.134. How to Report Sexually Transmitted Disease.
- (a) All case reports received by the health authority or the department are confidential records and not public records.
- (b) Reporting forms and/or information from all entities required to report should be sent to the local health department director where the physician's office, hospital, laboratory or medical facility is located or, if there is no such facility, the reports should be forwarded to the regional director in the region where the physician's office, hospital, laboratory, or medical facility is located.
- (c) If any individual or entity is unsure where to report any of the diseases mentioned in this title, the reports shall be placed in a sealed envelope addressed as follows: Texas Department of Health, HIV/STD Epidemiology Division, 1100 West 49th Street, Austin, Texas 78756 and the envelope shall be marked "Confidential." The envelope shall be delivered with the seal unbroken to the HIV/STD Epidemiology Division office for opening and processing of the contents. Postage paid envelopes may be obtained by contacting the HIV/STD Epidemiology Division and are provided without charge.
- (d) Reporting forms can be obtained from local health departments, regional offices, and the Texas Department of Health, HIV/STD Epidemiology Division, 1100 West 49th Street, Austin Texas, 78756. Forms shall be provided without charge to individuals required to report.
- (e) Reports of confirmed or suspected sexually transmitted diseases including AIDS and HIV infection must be submitted within seven days of the determination of the existence of a reportable condition.
- (f) Laboratories shall submit information weekly. If, during any calendar quarter, tests for chancroid, *Chlamydia trachomatis* infection, gonorrhea, HIV infection and syphilis are performed and all test results are negative, the person in charge of reporting for the laboratory shall submit a statement to this effect on or before January 5, April 5, July 5, and October 5 following that calendar quarter.

- (g) A local health director or regional director may authorize one or more employees under his/her supervision to receive the report from the physician by telephone and to physically complete the form; use of this alternative, if authorized, is at the option of the reporting physician. The local health department director or regional director shall implement a method for verifying the identity of the telephone caller when that person is unfamiliar to the employee.
- (h) A local health department director or regional director shall forward to the department at least weekly all reports of cases received by him/her. Transmittal may be by mail, courier or electronic transmission.
- (i) If reporting by electronic transmission, including facsimile transmission by telephone, the same degree of protection of the information against unauthorized disclosure shall be provided as those of reporting by mail or courier transmittal. The department shall, before authorizing such transmittal, establish guidelines for establishing and conducting such transmission.
- §97.139. Fee for Providing Written Notice of a Positive Human Immunodeficiency Virus (HIV)-Related Test Result to an Applicant for Insurance.
- **[(HIV)-Related Test Result to an Applicant for Insurance.**] An applicant for insurance must be given written notice of a positive HIV-related test result by a physician designated by the applicant, or in the absence of that designation, by the Texas Department of Health (department). If the department is requested to make this notification:
- (1) the form designated by the department for this purpose must be used. Copies of the form and other information concerning notification by the department may be requested from: Bureau of HIV and STD Prevention, 1100 West 49th Street, Austin, Texas 78756-3199. $\frac{1}{2}$ and
 - (2) (No Change.)
- §97.145 Anonymous and Confidential HIV Testing.
- (a) State-funded primary health, women's reproductive health, and sexually transmitted disease clinics shall provide voluntary, and affordable counseling and testing programs, both anonymous and confidential concerning HIV infection or provide referrals to those programs.
- (b) All HIV testing sites funded by the Texas Department of Health shall offer **[the option of]** confidential **and [or]** anonymous HIV testing on site.
- §97.146 Confidentiality of HIV/STD Test Results.

A test result is confidential. A person that possesses or has knowledge of a test result may not release or disclose the test result or allow the test result to become known except as provided by Health and Safety Code, §81.103 Confidentiality; Criminal Penalty. A person commits an offense

if, with criminal negligence and in violation of this section, the person releases or discloses a test result or other information or allows a test result or other information to become known. An offense under this section is a Class A misdemeanor.